(*b*) The Center for Veterinary Medicine may prepare its own summary of such data and information.

(3) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter.

(4) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a physician, hospital, or other institution.

(5) A list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in § 20.81 of this chapter.

(6) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 20.61 of this chapter.

(7) All correspondence and written summaries of oral discussions relating to the NADA, in accordance with the provisions of part 20 of this chapter.

(f) All safety and effectiveness data and information not previously disclosed to the public are available for public disclosure at the time any one of the following events occurs unless extraordinary circumstances are known:

(1) The NADA has been abandoned and no further work is being undertaken with respect to it.

(2) A final determination is made that the NADA is not approvable, and all legal appeals have been exhausted.

(3) Approval of the NADA is withdrawn, and all legal appeals have been exhausted.

(4) A final determination has been made that the animal drug is not a new animal drug.

(5) A final determination has been made that the animal drug may be marketed without submission of such safety and/or effectiveness data and information.

(g) The following data and information in an NADA file are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(h) For purposes of this regulation, safety and effectiveness data include all studies and tests of an animal drug on animals and all studies and tests on the animal drug for identity, stability, purity, potency, and bioavailability.

[40 FR 13825, Mar. 27, 1975, as amended at 42 FR 3109, Jan. 14, 1977; 42 FR 15675, Mar. 22, 1977; 54 FR 18280, Apr. 28, 1989]

EFFECTIVE DATE NOTE: At 67 FR 5057, Feb. 4, 2002, § 514.11 was amended in paragraph (a) by removing ''510.300'' and adding in its place ''514.80'', effective Aug. 5, 2002.

§ 514.12 Confidentiality of data and information in an investigational new animal drug notice.

(a) The existence of an INAD notice will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in an INAD file shall be handled in accordance with provisions established in § 514.11.

§ 514.15 Untrue statements in applications.

Among the reasons why an application for a new animal drug or animal feed bearing or containing a new animal drug may contain an untrue statement of a material fact are:

(a) Differences in:

(1) Conditions of use prescribed, recommended, or suggested by the applicant for the product from the conditions of such use stated in the application;

(2) Articles used as components of the product from those listed in the application;

(3) Composition of the product from that stated in the application;

(4) Methods used in or the facilities and controls used for the manufacture, processing, or packing of the product from such methods, facilities, and controls described in the application;

(5) Labeling from the specimens contained in the application; or

(b) The unexplained omission in whole or in part from an application or from an amendment or supplement to an application or from any record or report required under the provisions of section 512 of the act and § 510.300 or § 510.301 of this chapter of any information obtained from:

(1) Investigations as to the safety, effectiveness, identity, strength, quality, or purity of the drug, made by the applicant on the drug, or

(2) Investigations or experience with the product that is the subject of the application, or any related product, available to the applicant from any source if such information is pertinent to an evaluation of the safety, effectiveness, identity, strength, quality, or purity of the drug, when such omission would bias an evaluation of the safety or effectiveness of the product.

(c) Any nonclinical laboratory study contained in the application was not conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter, and the application fails to include a brief statement of the reason for the noncompliance.

[40 FR 13825, Mar. 27, 1975, as amended at 49 FR 7226, Feb. 28, 1984; 50 FR 7517, Feb. 22, 1985]

EFFECTIVE DATE NOTE: At 67 FR 5057, Feb. 4, 2002, § 514.15 was amended in paragraph (b) by removing ''§ 510.300'' and adding in its place ''§ 514.80'', effective Aug. 5, 2002.

Subpart B—Administrative Actions on Applications

§ 514.80 Records and reports concerning experience with approved new animal drugs.

The following table outlines the purpose for each paragraph of this section:

Purpose	Paragraph and Title
What information must be reported concerning approved NADAs or ANADAs?	514.80(a) Applicability
What authority does FDA have for requesting records and reports? Who is required to establish, maintain, and report required information relating to experiences with a new animal drug? Is information from foreign sources required?	514.80(a)(1)
What records must be established and maintained and what reports filed with FDA?	514.80(a)(2)
What is FDA's purpose for requiring reports?	514.80(a)(3)
Do applicants of Type A medicated articles have to establish, maintain and report information required under § 514.80?	514.80(a)(4)
How do the requirements under § 514.80 relate to current good manufacturing practices?	514.80(a)(5)
	514.80(b) Reporting Requirements
What are the requirements for reporting product/manufacturing defects?	514.80(b)(1) Three-day NADA/ANADA Field Alert Report
	514.80(b)(2) Fifteen-day NADA/ANADA Alert Report
What are the requirements for reporting serious, unexpected and adverse drug experiences?	514.80(b)(2)(i) Initial Report
What are the requirements for followup reporting of serious, unexpected adverse drug experiences?	514.80(b)(2)(ii) Followup Report
What are the requirements for reporting increases in the frequency of serious, expected and unexpected, and adverse drug experiences?	514.80(b)(2)(iii) Summary Report of Increased Frequency of Adverse Drug Experience
What are the requirements for nonapplicants for reporting adverse drug experiences?	514.80(b)(3) Nonapplicant Report